

STATUS OF THE CLAIMS

Claims 32-43 were pending in this application.

Claims 32-43 are rejected under 35 U.S.C. § 112, second paragraph.

Claims 32-43 are rejected under 35 U.S.C. § 102(b) as being anticipated by EP-A 349 150.

Claims 32-43 are rejected under 35 U.S.C. § 102(b) as being anticipated by EP-A 711 557 or WO 96/37192.

Claims 32-43 are rejected under 35 U.S.C. § 103(a) as being unpatentable over EP-A 349 150 or EP-A 711 557 or WO 96/37192 or WO 97/21428.

Claim 34 has been cancelled.

Claim 32 has been amended.

Claims 32-33 and 35-43 are presented for reconsideration.

REMARKS

Applicants propose to amend their claims in order to more particularly point out and distinctly claim an aspect of their invention. Thus the limits of claim 34 regarding component (b) have been incorporated in part into independent claim 32. Since claim 34 fails to further limit amended claim 32, it has been presently cancelled. Since no new matter has been added and the scope has been narrowed, entry of this amendment is respectfully solicited.

Claims 32-43 are again rejected under 35 U.S.C. § 112, second paragraph as indefinite, the examiner questioning what is meant by ", in which any cosmetically active agent is lipophilic and is always present as component (c)" in claim 32. Applicants respectfully note that claim 32 actually recites ", in which any cosmetically active agent is lipophilic and is always present in component (c)". This simply means that no lipophilic cosmetically active agents, which might be emulsified in the water phase to

which the homogeneous liquid comprising (a)-(d) is added, are additionally present. Applicants aver this is a clear and definite further limit on the claimed scope.

The examiner also again comments that claim 32 recites "which steps consist essentially of" and again asserts that claims 37-43 require additional steps and are therefore improper. Applicants respectfully note that the process of claim 32 results in a product, which is a cosmetic formulation of a lipophilic cosmetic active agent in the form of an aqueous highly homogeneous nanodispersion having a Gaussian distribution. They further note that here is nothing improper or indefinite in referring to a claim of a different statutory class for a definition of a term. See *Ex parte Porter*, 25 USPQ2d 1144 (BPAI, 1992). Composition claims 37-43 are directed to various commercial forms of products that contain the aqueous nanodispersion product as defined in claim 32 as one of their components. The fact that these commercial forms contain the product as defined in claim 32 as one of their components does not mean that these commercial forms cannot be made without additional process steps. A composition claim is clearly not limited to the process steps used to make one of its components. Applicants aver that how the commercial forms are subsequently made from the aqueous nanodispersion product as defined in claim 32 is totally irrelevant to the subject matter of claims 37-43.

It is respectfully submitted that all the claims submitted for reconsideration are in good formal order. Reconsideration and withdrawal of the rejection of claims 32-43 under 35 U.S.C. §112, second paragraph is therefore solicited.

Claims 32-43 are rejected under 35 U.S.C. § 102(b) as being anticipated by EP-A 349 150. The examiner asserts that the reference discloses the instant formulations (no formulations are claimed) and method. However the discussion of claim 32 on page 4 of the Office Action is factually incorrect. First of all the EP reverses the order of steps (α) and (β). In claim 32 no high shear is required in claimed step (β), wherein the non-aqueous phase prepared in step (α) and the water are mixed. This step wherein the non-aqueous phase and the water are mixed is precisely where EP employs a homomixer, i.e. high shear mixing. Applicants note page 5, lines 22-25, of the EP, where a homomixer is first used, "the component 6 [deionized water, mis-numbered in Table 1 since there are two 3)s -see Table 3] was gradually added, and a pressure emulsification [of the aqueous dispersion] was carried out by a Manton Gaulin."

As is well known, a Manton Gaulin is a high-pressure nozzle homogenizer, which is typically operated at a pressure of several hundred bar (= several thousand pounds per square inch). Thus the EP clearly fails to anticipate the claimed subject matter.

Claims 32-43 are also rejected under 35 U.S.C. § 103(a) as being unpatentable over EP-A 349 150. Since the EP clearly teaches and exemplifies a homomixer, i.e. high shear mixing, where claim 32 requires the absence of high shear or cavitation forces, the EP clearly teaches away from the claimed invention. How can it be obvious, from a reference, to do the opposite of what it teaches?

Reconsideration and withdrawal of all grounds of rejection of claims 32-34 over EP-A 349 150 is respectfully solicited in light of the remarks *supra*.

Claims 32-43 are rejected under 35 U.S.C. § 102(b) as being anticipated by EP-A 711 557 or WO 96/37192, both of record. Additionally they are also rejected under 35 U.S.C. § 103(a) as being unpatentable over both references.

The examiner acknowledges that U.S. Patent 5,658,898, which applicants supplied, is substantially equivalent to EP-A 711 557, yet repeats the statement "This rejection will be reconsidered upon submission of an English translation". Applicants respectfully note that since all U.S. Patents are in English, there is absolutely no basis for refusing to consider applicants' prior remarks. U.S. Patent 5,658,898 neither teaches nor suggests to use ethanol, and the subsequent mixing of the non-aqueous phase and water is with a Rannie High-Pressure Laboratory Homogenizer for 75 minutes at about 600 bar (see col. 9, line 40-49). Therefore, EP A 711 557 clearly neither teaches nor suggests the inventive process or the product-by-process physical forms obtainable thereby.

Reconsideration and withdrawal of all grounds of rejection of claims 32-34 over EP-A 349 150 (=U.S. Patent 5,658,898) is respectfully solicited in light of the remarks *supra*.

Re WO 96/37192, this publication is directed to the preparation of the pharmaceutical or cosmetic compositions comprising a sparingly soluble sphingolipid or glycolipid. Said compositions comprise:

- a) a sphingolipid or glycolipid,
- b) a phospholipid,
- c) a partial fatty acid ester of polyoxyethylene sorbitan,
- d) a carrier liquid,

- e) a therapeutic agent,
- f) a triglyceride and
- g) a water-soluble or lipid-soluble additive.

Essential component c) of these compositions is a partial fatty acid ester of polyoxyethylene sorbitan such as Tween 80. See page 26, last line and the discussion starting at page 11, line 1 and ending at page 12, line 3. Polyethoxylated sorbitan fatty acid esters such as Tween 80 are outside the amended scope.

Additionally, the carrier liquid d) is "water optionally admixed with C<sub>2</sub>-C<sub>4</sub>-alkanol" (page 13, line 5 of the WO). WO teaches to use 1 to about 10% of ethanol for injectable pharmaceutical formulations, but for cosmetic formulations, ethanol, isopropanol or mixtures thereof may be optionally admixed as C<sub>2</sub>-C<sub>4</sub>-alkanol. The amount of C<sub>2</sub>-C<sub>4</sub>-alkanol to use for cosmetic formulations is from 0.1 to about 10 %, with 0.1 to 2.0 % being preferred (page 13, lines 15-18). Hence the use of ethanol to form an aqueous dispersion is an optional expedient in WO.

On page 18, first paragraph of the WO, the preparation of the pharmaceutical or cosmetic compositions is disclosed. The process consists of 2 steps:

1. mixing components a), b), c) and d) and the optional components e), f) and g) and subjecting the dispersion to the steps
2.
  - a) addition of water (carrier), or
  - β) filtration and optionally dialysis and subsequent conversion of the dispersion into a dry preparation, or
  - γ) further processing the dispersion to the intended pharmaceutical dosage.

The proper test for anticipation is whether the instant method claims read on the methods taught in the reference. WO 96/37192 teaches to reverse the order of addition recited in claim 32, i.e. to add the water to the prephase rather than to add the prephase to the water as claimed. Further, essential component c) of the reference compositions, a partial fatty acid ester of polyoxyethylene sorbitan such as Tween 80, is outside the amended scope. Hence the rejection under 35 U.S.C. § 102(b) as being anticipated by WO 96/37192 is clearly erroneous.

Claims 32-43 are rejected under 35 U.S.C. § 103(a) as being unpatentable over WO 96/37192, cited above. In addition to teaching to reverse the order of addition recited in claim 32, i.e. to add the water

to the prephase rather than to add the prephase to the water as claimed, the WO fails to teach or suggest any component (b) as presently claimed.

Reconsideration and withdrawal of all grounds of rejection of claims 32-34 over WO 96/37192 is respectfully solicited in light of the remarks *supra*.

In addition to the § 103 rejections already discussed, claims 32-43 are rejected under 35 U.S.C. § 103(a) as being unpatentable over WO 97/21428. Applicants previously supplied a copy of CA 2,238,263, which is an English language equivalent of WO 97/21428. As the examiner acknowledges, this reference teaches pharmaceutical compositions comprising, as essential component b), a partial fatty acid ester of polyoxyethylene sorbitan such as Tween 80. See page 7, line 17 through page 9, line 5. Polyethoxylated sorbitan fatty acid esters such as Tween 80 are outside the amended scope. No other emulsifiers are suggested. Hence WO 97/21428 (= CA 2,238,263) neither teaches nor suggests the presently claimed invention.

Reconsideration and withdrawal of the rejection of claims 32-43 under 35 U.S.C. § 103(a) as being unpatentable over WO 96/37192 is therefore respectfully solicited.

Since there are no other grounds of objection or rejection, passage of this application to issue with claims 32-43 is earnestly solicited.

Applicants submit that the present application is in condition for allowance. In the event that minor amendments will further prosecution, Applicants request that the examiner contact the undersigned representative.

Respectfully submitted,



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